REMARKS

Status of the Claims

Claims 26, 28, 29, 54-60, 66-68, 70-78 and 80-82 are pending in the application.

Summary

Claims 26, 28, 29, 54-60, 66-68, 70-78 and 80-82 are pending in the application and were examined in the Office Action dated 30 July 2008. Applicants note with appreciation that the Office has withdrawn the objection to the drawings under 37 C.F.R. §1.83. However, the Office has raised the following claim rejections: **(a)** claims 26, 28-29, 66-68, 70-71, 75-78 and 80-82 have been rejected under 35 U.S.C. §103(a) as unpatentable over International Publication WO 97/38698 to Manning et al. ("Manning"); **(b)** claims 54-60 have been rejected under 35 U.S.C. §103(a) as unpatentable over Manning; and **(c)** claims 72-74 have been rejected under 35 U.S.C. §103(a) as unpatentable over Manning in view of U.S. Patent No. 4,472,394 to Peterson ("Peterson"). Applicants respectfully traverse all pending claim rejections for the following reasons.

The Rejections under 35 U.S.C. §103

Claims 26, 28-29, 66-68, 70-71, 75-78 and 80-82 have been rejected under 35 U.S.C. §103(a) as unpatentable over Manning. In support of its rejection, the Office asserts that Manning "discloses the invention substantially as claimed" and that applicants' recited drug delivery structures would have been a "mere design choice". Office Action at pages 3 and 4. Applicants respectfully disagree.

When considering the patentability of claims under Section 103, the following tenets of patent law must be adhered to: (a) the claimed invention must be considered as a whole; (b) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (c) the references must be viewed

with the benefit of impermissible hindsight vision afforded by the claimed invention; and (c) reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Co., Inc.*, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986). It is clear that once these tenets are applied to the instant rejection, the rejection cannot stand.

Applicants' claims recite novel methods whereby a drug delivery unit (having structure and shape specifically designed for insertion directly into the round window niche so as to be positioned within the round window niche. Manning's method entailed flooding of the middle ear with a volume of liquid that fills at least one quarter of the entire middle ear. Manning does not teach or disclose insertion of a drug unit directly into the subject niche, rather Manning floods the middle ear and lets some of the therapeutic eventually reach the niche. Manning likewise does not teach or disclose positioning a drug unit completely within the niche. The majority of the therapeutic administered by Manning will not be contained within the round window niche, and it therefore will not even contact the round window membrane. In addition, Manning's methodology is not efficient in that majority of the therapeutic drains out of the middle ear within the first day of delivery, and Manning's methodology is not safe in that a very large amount of the therapeutic is administered to other parts of the middle ear where toxic agents can cause actual harm to the sensitive middle ear tissue.

Applicants' claimed methods are a significant improvement over the art such as Manning, where a therapeutic can now be very specifically inserted directly into the target niche, avoiding potential inadvertent and harmful delivery to other tissue (important if ototoxic compositions are used), and ensuring direct delivery through the round window membrane for the duration of the controlled delivery event (hours, days, or even months). Applicants' recited methods are not simply "mere design choices" and they are neither taught nor suggested in any way by the Manning reference. Manning completely fails to teach or disclose administration of a shaped drug unit configured as a pellet, disk, tablet, plate, sphere, cube, cylindrical unit, strand, or plug. Manning does not teach the placement of drug delivery unit directly into the round window niche. As discussed herein above, this feature provides significant efficiency and safety advantages.

Even though Manning would presumably have been aware of the issues of safety (toxicity) and efficiency, Manning completely failed to teach or suggest applicants' recited methodology. This is strong and compelling evidence of non-obviousness. Since Manning failed to teach or suggest placement of drug delivery unit directly into the round window niche, and instead taught flooding of a large portion of the entire middle ear instead, it cannot possibly have enabled applicants' recited methods. An utter lack of any teaching or suggestion cannot possibly be considered enabling.

For all of the foregoing reasons, then, the rejection of claims 26, 28-29, 66-68, 70-71, 75-78 and 80-82 under 35 U.S.C. §103(a) is improper. The Office has simply failed to identify any teaching or suggestion in Manning that would lead to applicants' recited methodology. The naked argument that applicants' significant departures from the prior art are "merely design choices" is not supported by any facts or evidence of record and thus cannot establish a *prima facie* showing of obviousness under any circumstances. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

Claims 54-60 stand rejected under 35 U.S.C. §103(a) as unpatentable over Manning. In particular, the Office again asserts that Manning "discloses the invention substantially as claimed," and that the selection of a biocompatible polymer "is not critical to the invention." (Office Action at page 5.) Applicants respectfully disagree.

As established herein above, Manning's method of flooding the entire middle ear cannot render applicants' recited methods of providing specially shaped and configured drug delivery devices that are inserted directly into the round window niche. Accordingly, there is simply no facts or evidence of record that establishes a *prima facie* showing of obviousness over Manning. Accordingly, the rejection of claims 54-60 under 35 U.S.C. §103(a) is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

Claims 72-74 stand rejected under 35 U.S.C. §103(a) as unpatentable over Manning in view of Peterson. Here again, the Office again asserts that Manning "discloses the invention substantially as claimed," and then looks to Peterson for a teaching of implanting a pellet below the ear of a farm animal. (Office Action at pages 5 and 6.) Applicants respectfully disagree.

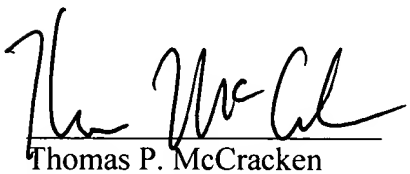
As discussed above, the primary reference to Manning does not even come close to teaching or suggesting applicants' novel methods. Applicants quite frankly do not follow the Office's reasoning that the Peterson implants could somehow overcome all of the shortcomings of Manning methodology, and lead to applicants' specifically shaped and configured drug delivery devices that are custom designed for insertion directly into the round window niche. There are simply no facts or evidence of record in this case that would support such an assertion. Accordingly, the rejection of claims 72-74 under 35 U.S.C. §103(a) is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

CONCLUSION

Applicants submit that the pending claims define an invention that is both novel and nonobvious over the cited art, and thus all claims are in condition for allowance. Acknowledgement of this by the Office in the form of an early allowance is thus respectfully requested. In addition, if the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, applicants invite the Examiner to contact the undersigned at (408) 777-4915.

The appropriate fee is attached or authorized. If the Commissioner determines that an additional fee is necessary, the Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. **50-1953.**

Respectfully submitted,



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